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COMMENTS ON DEPARTMENT OF HEALTH AND HUMAN SERVICES PROPOSED RULE 45 CFR PARTS 160-164

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

DUPLICATE SUBMISSION--ALSO SUBMITTED ON FLOPPY DISK

Submitted by:
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On behalf of:
New Mexico Task Force on Health Data Privacy and Confidentiality

Submitted to:
U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Attention: *Privacy-P
Room G-322A, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

These comments are submitted by the New Mexico Task Force on Health Data Privacy and Confidentiality, convened in 1999 by the New Mexico Health Policy Commission to develop consensus on the privacy and confidentiality of health information, make recommendations for changes in state statutes, and comment on proposed federal regulatory actions. The 27-member Task Force is comprised of individuals and organizations with an interest in the appropriate use of individual health data. The Task Force offers the following comments on the Department of Health and Human Services' proposed rule 45 CFR Parts 160-164. While a majority of the active members of the Task Force supports these comments, individual members may have disparate views on certain points.

GENERAL COMMENTS

1. The provisions permitting disclosure of protected health information without an individual's authorization for treatment, payment or health care operations are too broad and sweeping. These should be narrowed as follows:

   - Disclosure for treatment: The permissible disclosure should be limited to only what is necessary for treatment, with patient control over who receives the information.

- Disclosure for payment: The permissible disclosure should be limited to only what is necessary to identify the individual, the provider, the date of service, and the diagnostic code(s).

- Disclosure for health care operations: The permissible disclosure should be limited to only de-identified information to the extent feasible.

2. De-identified health information should be used wherever possible instead of individually identifiable information.

3. An individual's right to request amendment or correction of protected health information should extend to all information held by the covered entity, including information that may be considered irrelevant or untimely.

4. The responsibility for correcting protected health information should extend to any covered entity notified of an individual's request for correction, not just the original creator of the information.

5. The proposed rule should apply to all individually identifiable health information, not just information that is maintained or transmitted electronically.

COMMENTS ON SPECIFIC PROVISIONS OF THE PROPOSED RULE

Definitions

"Designated record set" in § 164.504: This definition unreasonably restricts the amount and type of personal information individuals would be permitted to access. First, the definition should not limit the records to those from which information "is retrieved" by a covered entity. Doing so undermines the right of individuals to review all of their protected health information, not just the information the entity chooses to retrieve. Instead, the information should be "retrievable," meaning that a protected entity could obtain the information if it tried. Second, the definition should not limit the records to those used by a covered entity to make decisions about an individual. Clearinghouses do not make decisions about an individual, yet "designated record set" is associated with clearinghouses in subsequent provisions of the proposed rule. A decision-making requirement is irrelevant to the scope of protected health information accessible to individuals. The Task Force recommends the following changes.

> ***Designated record set*** means a group of records under the control of a covered entity from which information is ~~retrieved~~ retrievable by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual ~~and~~ . . For purposes of this paragraph, the term ***record*** means any item, collection, or grouping of protected health information maintained, collected, used or disseminated by a covered entity.

"Protected health information" in § 164.504: The blanket exclusion of inmate and detainee health information from this definition goes far beyond satisfying the special information needs

of correctional and detention facilities. Instead of completing obliterating any right to health information privacy for inmates and detainees, the rule should authorize the release of protected health information on a "need to know" basis. Given the complexities and sensitivities of correctional services, the Task Force declines to recommend specific changes in wording.

"Public health authority" in § 164.504: This definition should be expanded to encompass other governmental entities that may collect and hold health data as part of their official duties. The Task Force recommends the following changes.

> ***Public health authority*** means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe that is responsible for public health matters or the collection of health data as part of its official mandate.

Introduction to General Rules

In § 164.506(a)(l), the permissible disclosure of protected health information "to carry out treatment" is too broad for health plans, which are covered entities. Health plans that have no responsibility for treatment or care coordination should have no authority to release health information without authorization for "treatment" purposes. The Task Force recommends the following changes.

> (1) ***Permitted uses and disclosures.*** A covered entity is permitted to use or disclose protected health information as follows:
> (i) Except for research information unrelated to treatment, to carry out treatment, payment, or health care operations, to the extent the covered entity engages in these activities;

In § 164.506(c)(l), the right of individuals to request restrictions on disclosure of their protected health information, with certain exceptions, is meaningless because covered entities have no obligation to honor the request. To effectuate the principle of individual control over one's own health care information, requests for restrictions should not be subject to blanket denial. Instead, the rule should contain standards for assessing and complying with or rejecting these requests. Additionally, this section should clarify that individual restrictions on disclosures do not apply to disclosures required by state law and permitted by the federal rule. The Task Force recommends the following changes.

> (c)(1) ***Standard: Right of an individual to restrict uses and disclosures.***
> (i) A covered entity that is a health care provider must permit individuals to request that uses or disclosures of protected health information for treatment, payment, or health care operations be restricted, ~~, and, if the requested restrictions are agreed to by t~~ The provider; must grant the request. and not make uses or disclosures inconsistent with such restrictions:, under the following conditions:
> [to be specified; no language offered]
> (ii) This requirement does not apply:
> (A) To uses or disclosures permitted under § 164.510;

(B) When the health care services provided are emergency services or the information is requested pursuant to § 164.5 1 O(k); and
(C) To disclosures to the Secretary pursuant to §164.522.; and
(D) To disclosures reauired bv law and permitted under 6 164.5 10.

Individual Authorization

In §164.508(a)(iv), the prohibition on requiring authorization for release of protected health information for treatment, payment or health care operations is unreasonable and unnecessary. Section 164.508(a)(iii) protects the patient from undue pressure or coercion by a specific prohibition on conditioning treatment or payment on receipt of a requested authorization. Health care professionals who prefer to obtain a signed authorization for self-protection against future accusations of unauthorized disclosure, especially for health care operations purposes, ought to be able to require one. The Task Force recommends deletion of this provision.

Introduction to Uses and Disclosures Without Individual Authorization

In § 164.510(a), the provision should specifically and clearly state that disclosures which are merely permissive under the rule may be mandatory under other law, including state law, thereby eliminating any discretion about disclosing the information. The Task Force recommends the following changes.

(a) ***General requirements.*** In using or disclosing protected health information under this section:
....
(3) *Mandatory* ***disclosures.*** Disclosures that are permissive under this section may be required by other laws. Covered entities are responsible for complying with the disclosure requirements of other laws, including state laws, provided the disclosures are permissible under this rule.

Law Enforcement

In §164.510(f)(3), the provision authorizing disclosures in certain situations of a crime victim's protected health information may result in further harm to the victim. For example, undesired release of personal health information to law enforcement officers concerning victims of sexual assault or domestic violence may compromise the victim's personal safety, integrity or dignity. The rule should allow disclosure only if the victim consents, or is unable or unavailable to consent. As always, permitted disclosures should be limited to the minimal amount of information necessary for the specific purpose. The Task Force recommends the following changes.

(3) Information about a victim of crime or abuse. The disclosure is of the protected health information of an individual who is or is suspected to be a victim of a crime, abuse, or other harm, if the law enforcement official represents that:
(i) Such information is needed to determine whether a violation of law by a person other than the victim has occurred; and

(ii) Immediate law enforcement activity that depends upon obtaining such information may be necessary:&
(iii) The victim has consented to the disclosure. or is unable or unavailable to consent.

Directory Information

In § 164.510(h)(2), the rule should address authorizations granted by legal representatives on behalf of incapacitated individuals. Many states have laws governing substitute decision making for incapacitated individuals, including provisions on surrogates, agents and guardians. The Task Force recommends the following changes.

(h) ***Disclosures of directory information.***
(1 ***) Individuals with capacity and*** *incapacitated* ***individuals with a*** *legal representative.* For individuals with the capacity to make their own health care decisions, or incapacitated individuals with a legal reoresentative, a covered entity that is a health care provider may disclose protected health information for directory purposes, provided that the individual or legal representative has agreed to such disclosure.
(2) Incapacitated individuals *without* ***a*** *legal representative.* For individuals who are incapacitated and have no legal reoresentative, a covered entity that is a health care provider may, at its discretion and consistent with good medical practice and any prior expressions of preference of which the covered entity is aware, disclose protected health information for directory purposes.

Banking and Payment Processes

In § 164.5 10(i), the permitted disclosure for "routine banking activities" may be read too expansively for adequate protection of an individual's health information. While the Task Force recognizes that in some situations protected health information necessarily must be disclosed for banking and payment purposes, there should be a clear restriction on any broader disclosure or use. The Task Force recommends that this section be more clearly and narrowly worded to encompass only necessary and unavoidable disclosures for the specified purposes.

Access for Inspection and Copying

In § 164.514(a), a designated record set is too limited in scope to encompass all of the protected health information that an individual should be able to see, copy and correct, which should extend to all of the electronic data established or maintained on the person. The Task Force recommends the following changes, which should be made in parallel fashion in § 164.516(a) and wherever designated record set is referenced in the proposed rule.

(a) ***Standard; Right of access.*** An individual has a right of access to, which includes a right to inspect and obtain a copy of, his or her protected health information ~~in designated records sets of~~ held by a covered entity that is a health plan or a health care provider, including such information ~~in~~ held by a business partner- that is not a duplicate of the information held by the provider or plan, for so long as the information is maintained.

In § 164.514, the provisions authorizing denial of access to an individual's own protected health information allow health care professionals unchecked discretion over what information individuals are allowed to know about their own health. The United States has quite an unfortunate, blemished history of physicians acting-or experimenting-on behalf of their own interests, not their patients' interests, or out of questionable notions of paternalism. The rule should provide a necessary constraint on health care professional discretion while nonetheless acknowledging the exceptional circumstances that may justify denial of access. The Task Force recommends the following new subsection be added to § 164.514(d).

> (d)(5) *Request denied—additional procedures.* When a request is denied in whole or in part, the covered entity shall, to the extent feasible, segregate the protected health information to which access is denied from information to which access is not denied and permit the individual to inspect or copy the disclosable information. The covered entity shall inform the individual of the partial or whole denial of access and permit inspection and copying of the denied information by another health care provider, selected by the individual, who is licensed, certified or otherwise authorized by law to treat the individual for the same condition. The covered entity shall inform the individual of the right to select another health care provider for this purpose.

Accounting of Disclosures

In § 164.515(a), the exclusion of disclosures for treatment, payment and health care operations from the accounting of disclosures is of grave concern to the Task Force. While recognizing that the task of tracking and recording these disclosures may be burdensome, the fact that consent is not required initially for the disclosures means that individuals have no right to consent to or be made aware of a multitude of ways in which their protected health information may be used. The Task Force sees no easy solution to the balancing of interests here, but fears that the lack of accountability increases the risk of misuse and abuse of private health information. One suggestion is to include disclosures made outside of a facility for treatment, payment and health care operations in the accounting available to the individual. This differentiation would acknowledge that individuals reasonably can expect disclosures for these purposes within the treating facility, but should be able to find out about disclosures made outside of it.

CONCLUSION

The Task Force on Health Data Privacy and Confidentiality and the New Mexico Health Policy Commission appreciate the opportunity to comment on the proposed rule.

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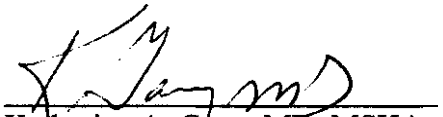

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On behalf of the New Mexico Task Force on Health Data Privacy and Confidentiality

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Date of Submission